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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,745	01/16/2001	Gunter Schmidt	PM-0276612	7328

909 7590 10/01/2003

PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/01/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,745

Applicant(s)

SCHMIDT ET AL.

Examiner

Patrick T. Lewis

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6-7</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Objections

1. Claims 5-30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-30 not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974). The essential novelty, the essence of the invention, must be describe in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

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The instant specification is drawn to a compound of formula (I) wherein M comprises a mass marker, N comprises a nucleic acid, and wherein R¹ and R² are each independently selected from a hydrogen atom, a substituted or unsubstituted alkyl group, and a substituted or unsubstituted aryl group. Presently, the examples in the instant specification are limited to the preparation of a mass labeled nucleotide FT23 and mass spectrometry analysis of FT23. Applicants do not provide an adequate written description which provides guidance for the preparation of compounds of formula (I) as instantly claimed. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. The process is considered to be incomplete wherein applicant does not set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms (e.g. all moieties "substituted" wherein the identity of the substituent intended to effectuate said substitution are not set forth in any synthetic procedural steps).

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400. The factors include: 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the

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predictability of the art, and 7) the breadth of the claims. In the instant case no guidance is provided for preparing the instantly claimed compounds. No working examples are provided (for synthesis of instantly claimed compounds). Indeed with the very limited disclosure provided by applicant, it would require undue experimentation by one of ordinary skill in the art to make the instantly claimed compounds of formula (I).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrases "M comprises" and "N comprises" render all claims wherein the variables "M" and "N" are not distinctly described indefinite as one of ordinary skill in the art would not be apprised of the metes and bounds of the instantly claimed compounds.

The phrase "wherein the nucleotide or oligonucleotide is natural, or is modified" and term "substituted" render the claims in which they appear indefinite. In the absence of distinct modifications to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of modified/substituted compounds of this invention, the identity of said modified/substituted compounds would be difficult to describe and the metes and bounds of said modified compounds applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawson et al. *Journal of the American Chemical Society* (1971), Vol. 93, pages 1014-1023 (Lawson).

The instant invention is drawn to a compound of formula (I) wherein M comprises a mass marker, N comprises a nucleic acid, and wherein R¹ and R² are each independently selected from a hydrogen atom, a substituted or unsubstituted alkyl group, and a substituted or unsubstituted aryl group. The term "mass marker" has been interpreted broadly to mean any moiety having a mass detectable by any means known in the art at the time of the invention. As such, the instantly claimed compounds of formula (I) are anticipated by Lawson. Lawson discloses trimethylsilyl derivatives of nucleotides corresponding to instantly claimed formula (I) wherein N is a nucleotide and R¹, R², and M are methyl groups (page 1014, compounds 1-9).

Conclusion

8. Claims 1-30 are pending. Claims 1-4 are rejected. Claims 5-30 are objected to. No claims are allowed.

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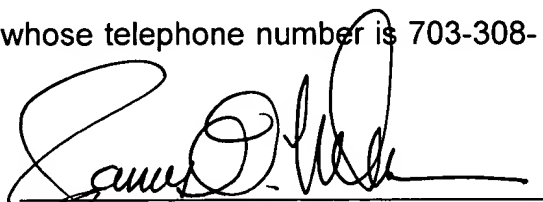
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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